Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Rituxan® (Rituximab)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***June 2006 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *October 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Rituxan® (rituximab) for non-cancer diagnoses.

Rituxan® (rituximab) is indicated:

- For the treatment of patients with:
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell Non-Hodgkin's Lymphoma (NHL) as a single agent
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan® (rituximab) in combination with chemotherapy, as single-agent maintenance therapy
  - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line CVP chemotherapy
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens
- In combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive Chronic Lymphocytic Leukemia (CLL)

- In combination with methotrexate, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies
- In combination with glucocorticoids, for the treatment of adult patients with Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)
- Moderate to severe pemphigus vulgaris in adults

Medical oncology agents are approved based on FDA approved and/or compendia-supported indications. Off-label requests for medical oncology agents are reviewed in accordance with RX.013.

DEFINITIONS

CVP Chemotherapy – cyclophosphamide, vincristine, and prednisone

CHOP Chemotherapy – cyclophosphamide, doxorubicin, vincristine, and prednisone

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Rituxan® (rituximab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. Rheumatoid Arthritis

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate with an inadequate response
- Must have an adequate trial (of at least 3 months each) of Enbrel® AND Humira® with inadequate responses, significant side effects/toxicities, or a have a contraindication to these therapies

- Must be on concurrent methotrexate therapy
- Must currently not be using a TNF-blocking agent or other biologic agents in combination with Rituxan®
- Must currently not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
- Must have no evidence of severe, active infection

2. Granulomatosis with Polyangiitis (GPA)/Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of Granulomatosis with Polyangiitis/Wegener's Granulomatosis or Microscopic Polyangiitis
- For induction therapy, must be on concomitant therapy with glucocorticoids
- For maintenance therapy, must have an adequate trial (of at least 3 months) of azathioprine or methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have no evidence of severe, active infection

3. Renal and/or Pancreatic Transplant Desensitization in Combination with IVIG

- Must be prescribed by a transplant specialist
- Must be age 18 years or older
- Must currently not have PML or have a history of PML
- Must be awaiting kidney and/or pancreas transplant requiring desensitization as defined by:
    - For deceased donor transplants, must have one of the following:
        - Panel reactive antibody (PRA) level >30%
        - PRA <30% with a previous kidney and/or pancreas transplant
    - For living donor transplants, must have the following:
        - Positive crossmatch
        - Positive donor-specific antibody using Luminex® assay

4. Oncology

- Must be prescribed by an oncologist or hematologist
- For Non-Hodgkin's Lymphoma (NHL), must be used for:

  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan® in combination with chemotherapy, as single-agent maintenance therapy
  - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line CVP chemotherapy
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens
- For Chronic Lymphocytic Leukemia (CLL), must be used:
  - In combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL

5. Pemphigus Vulgaris (PV)

- Must have a diagnosis of biopsy-proven moderate to severe pemphigus vulgaris
- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must currently not have PML or have a history of PML
- Must have an adequate trial of at least one of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
  - Immunosuppressants (such as azathioprine or methotrexate)
  - Corticosteroids
- In rapidly progressive, extensive, or debilitating cases (i.e. Stevens Johnson Syndrome), Rituxan may be approved along with corticosteroids or immunosuppressive agents

Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for the continuation of treatment. Authorization is extended as specified below:

1. Rheumatoid Arthritis:

- For an additional course of treatment, based upon review of documentation from the prescriber indicating that the member's condition has improved as a result of

therapy. Authorization is not granted until 16 weeks has passed since the previous treatment.

2. Granulomatosis with Polyangiitis/Wegener's Granulomatosis and Microscopic Polyangiitis:

- For an additional 6 months, based upon review of documentation from the prescriber indicating that the member is continuing to benefit from treatment.

3. Renal and/or Pancreatic Desensitization Candidates:

- For an additional course of treatment (with the above regimen) if the member has not yet received a renal and/or pancreatic transplant. Authorization is not granted until 6 months have passed since the initial treatment.

4. Oncology

- For an additional 6 months, based upon review of documentation from the prescriber indicating that the member's is continuing to benefit from treatment

4. Pemphigus Vulgaris (PV)

- For an additional course of treatment, based upon review of documentation from the prescriber indicating that the member's condition has improved as a result of therapy. Authorization is not granted until 12 months has passed since the initial treatment and 6 months for every subsequent treatment after the second treatment course.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• RA and PV: 1 course of treatment (two 1000mg doses given on day 1 and 15) • WG and MPA: 1 month • Transplant Desensitization: 1 course of treatment (one 1000mg dose given on day 15) • Oncology: 6 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Reference update	*10/16*
Criteria update	*12/16*
New Indication	*10/18*